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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,801	12/03/1999	Saswati Chatterjee	1954-287	3067

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/453,801

Applicant(s)

CHATTERJEE ET AL.

Examiner

Gerald Leffers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of an amendment, filed 1/17/02 as Paper No. 11, in which nonelected claims were cancelled (claims 24-33) and in which claims were amended (claims 12-13 and 23). As part of Paper No. 11, declarations were submitted under 37 C.F.R. §§ 1.131 and 1.132. These declarations have been fully considered.

Claims 1-23 are pending in this application. Any rejection of record in Paper No. 9 not addressed in this action has been withdrawn. Rejections made below are maintained for reasons of record in Paper No. 9. This action is FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 23 are vague and indefinite in that the metes and bounds of the term “stably transfecting” are unclear. **This rejection is maintained for reasons of record in Paper No. 9, mailed 7-18-01 and repeated below.**

The term does not appear to be explicitly defined in the specification and is inherently indefinite. How many generations does the transferred DNA have to be present in the transduced cell for it to be considered “stably” transferred? It would be remedial to amend the claim

language to clearly indicate what is intended by the limitation of “stably transferring” a DNA into the target cells.

Response to Arguments

Applicant's arguments filed in Paper No. 11 have been fully considered but they are not persuasive. The response essentially argues: 1) the specification at page 14, lines 27-28 describes integration as being at least 4 weeks, 2) claim 12 has the specific limitation of at least 4 weeks, and 3) claim 1 must therefore be read at least as broadly as claim 12.

The passage cited by the response merely indicates that the methods of the invention can result in stable integration for at least 4 weeks, 8 weeks or much longer. This is not a definition of the term “stably” transformed and does not indicate a minimum time for “stable” integration of at least 4 weeks. Moreover, applicants’ argument that because dependent claim 12 specifies “at least 4 weeks” one must read claim 1 at least as broadly is confusing and is not accurate. Claim 12 merely limits the time that one may consider for “stable integration” as being at least 4 weeks. This does not mean that the term “stably transferred” in claims 1 and 23 can’t embrace embodiments wherein integration is present for only 1-3 weeks. The term “stably transferring” remains vague and indefinite despite the arguments presented in applicants’ response. It would be remedial to provide a functional limitation to help define the metes and bounds of the term “stably transferring” (e.g. for at least 4 weeks).

Claim 2 is vague and indefinite in that the metes and bounds of the phrase “...the cells in G0 phase do not differentiate or undergo mitosis substantially during the transduction

process" are unclear. **This rejection is maintained for reasons of record in Paper No. 9, mailed 7-18-01 and repeated below.**

What level of differentiation or mitotic activity within the target cell population would constitute "substantial" activity? It would be remedial to amend the claim language to more clearly indicate what constitutes "substantial" cell differentiation or mitotic activity for the transduced cell population.

Response to Arguments

Applicant's arguments filed in Paper No. 11 have been fully considered but they are not persuasive. The response essentially argues: 1) the term "substantially" has been recognized as definite by the Office (MPEP 2173.05(b), and 2) the specification provides ample guidance with regard to what constitutes "substantial" differentiation or mitotic activity.

While the Office has recognized that the term "substantial" is definite in some cases, the term must be evaluated in each case in light of the specification.

M.P.E.P. 2173.05(b) Relative Terminology

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

The passage cited by applicants' response as providing ample guidance to the skilled artisan to determine the metes and bounds of the words "substantial activity" do not definitively provide limits as to what constitutes substantial activity. The cited passage states "The cells substantially remain in G0 for at least about 2 days or up to about 7 days, or longer. After about 7 days in culture, greater than 80% of the transduced stem cells can remain in G0. Generally, cells of the invention are about 92 to 99% non-dividing after about 2 days and about 65% to

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about 83% non-dividing after about 7 days of culture. Thus, the cells do not differentiate at an appreciable rate.” The passage provides only a general outline of the characteristics of the cells of the invention but does not provide definite limits. For example, what day post transduction would one necessarily make a measurement of cell state in order to determine substantial activity? Does the passage necessarily limit one to the 2 to 7 day window? What percentage of cells remaining in G0 after a period of time would allow a cell population to satisfy the criteria for displaying “substantial” differentiation or mitotic activity? For example, would a population of cells having 95% non-dividing cells after 2 days but having only ~60% non-dividing cells after 7 days be considered as displaying no “substantial” mitotic activity? The term remains indefinite, even in light of the specification.

Claim 6 is vague and indefinite in that the metes and bounds of the term “low cytokine levels” are unclear. **This rejection is maintained for reasons of record in Paper No. 9, mailed 7-18-01 and repeated below.**

Although the specification lists preferred levels for three cytokines, it is not clear that the term “low cytokine levels” has been explicitly defined by this information. Also, it is not clear how the term would apply to other cytokines not addressed by the specification. It would be remedial to amend the claim language to clearly indicate what is intended by the cited term.

Response to Arguments

Applicant's arguments filed in Paper No. 11 have been fully considered but they are not persuasive. The response essentially argues that the specification provides ample examples or guidance as to what constitutes “low cytokine levels” and cites a particular passage wherein low

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cytokine levels are linked to the functional limitation that "hematopoietic stem cells in culture remain quiescent and mitotically dormant for up to 2 days (48 hours) or even longer" (pages 13-14, bridging paragraph). The cited passage does not indicate, however, what percentage of the population of hematopoietic stem cells must remain dormant for at least 48 hours in order to meet the functional limitation. Does the cited passage imply that every stem cell in the population must remain dormant? If not, then what percentage of the cells must remain dormant in order to meet the limitation? Without knowing this, the functional limitation of not inducing mitotic activity in the hematopoietic stem cell population has applicability in determining what constitutes a "low level" of a cytokine.

Claim 16 is vague and indefinite in that the metes and bounds of the term "derived from" are unclear. **This rejection is maintained for reasons of record in Paper No. 9, mailed 7-18-01 and repeated below.**

It is unclear the nature and number of steps required to generate an AAV vector "derivative" of the vector CWRSV".

Response to Arguments

Applicant's arguments filed in Paper No. 11 have been fully considered but they are not persuasive. The response essentially argues the specification provides significant guidance and examples wherein vectors are obtained from the vector CWRSV. This argument is not persuasive in that the minimal functional elements required for a vector to be considered as "derived from" CWRSV remain unclear, even in light of the embodiments exemplified in the instant specification. For example, would an AAV vector comprising only 50% identity to

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CWRSV constitute a “derivative”? It would be remedial to amend the claim language to include functional limitations sufficient for one of skill in the art to be able to determine that a particular AAV vector is a “derivative” of CWRSV.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

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ggl
April 6, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo